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510(k) SUMMARY

AUG 11 2006

SUBMITTER NAME: Ascension Orthopedics, Inc.
8700 Cameron Road, C-100
Austin, TX 78754-3832

510(k) CONTACT: Glen Neally
Ph: (512) 836-5001

TRADE NAME: Ascension® CMC

COMMON NAME: prosthesis, wrist, carpal trapezium

CLASSIFICATION: 21 CFR §888.3770 Wrist joint carpal trapezium polymer prosthesis

PRODUCT CODE: KYI

PANEL: Orthopedic Devices

PREDICATE DEVICE: Ascension® PHS, (K041451)

DEVICE DESCRIPTION:
The Ascension® CMC is intended for use as a hemi joint replacement for the base of the first metacarpal of the carpometacarpal (CMC) joint. The Ascension CMC is a one component prosthesis having a saddle configuration articular surface which bears against the mating saddle articular surface of the trapezium. The saddle design allows for flexion-extension joint motion and abduction-adduction motion. It is designed to be a press fit device. Each device is comprised of a pyrocarbon layer encasing a machined graphite substrate. The graphite substrate material is impregnated with a small amount (1 atomic percent) of tungsten. This small amount of tungsten renders the graphite substrate radiopaque. The device is provided sterile in packaging containing a single device.

INTENDED USE:
The Ascension® CMC is intended to replace the proximal end of the first metacarpal in cases of rheumatoid arthritis, traumatic arthritis, osteoarthritis or post fracture deformation or bone loss which present as either a painful, unstable thumb, or a thumb with limited range of motion. This is an uncemented prosthesis designed for press fit use only.

BASIS OF SUBSTANTIAL EQUIVALENCE:
Performance tests conducted on Ascension CMC devices, in vitro material biocompatibility tests, and pre-clinical animal tests demonstrate that the Ascension CMC is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 11 2006

Ascension Orthopedics, Inc.
% Mr. Glen Neally
VP of QA/RA/CA
8700 Cameron Road, Suite 100
Austin, Texas 78754

Re: K061451
Trade/Device Name: Ascension® CMC
Regulation Number: 21 CFR 888.3770
Regulation Name: Wrist joint carpal trapezium polymer prosthesis
Regulatory Class: Class II
Product Code: KYI
Dated: May 22, 2006
Received: May 25, 2006

Dear Mr. Neally:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k)

premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(K) Number: K061451

Device Name: Ascension® CMC

Indications for Use: The Ascension® CMC is intended to replace the proximal end of the first metacarpal in cases of rheumatoid arthritis, traumatic arthritis, osteoarthritis or post fracture deformation or bone loss which present as either a painful, unstable thumb, or a thumb with limited range of motion. This is an uncemented prosthesis designed for press fit use only.

Prescription Use ___X___ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lurlene Hudson for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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